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Application  
Atty. Docket No. 0501-UTL-0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. Serial No.: 10/559,595

Inventors: John ONG, et al

Filed: November 30, 2005

Title: NOVEL METHODS AND COMPOSITIONS  
FOR ENHANCED TRANSMUCOSAL DELIVERY OF  
PEPTIDES AND PROTEINS

Confirmation No.: Not Yet Assigned

TC/A.U.: Not Yet Assigned

Examiner: Not Yet Assigned

TRANSMITTAL LETTER

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The following documents are enclosed herewith for your review and consideration:

- Information Disclosure Statement under 37 CFR 1.56 (2 pages)
  - Including 25 copies of references
- PTO SB08 Form (4 pages)
- Return Post Card

Respectfully submitted,  
AMYLIN PHARMACEUTICALS, INC.

Dated: March 9, 2006

By: *Timothy E. Torchia*  
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3/9/06  
Date of Deposit

*William C. Hines*  
Signature of Person Mailing Paper  
*William C. Hines*  
Name of Person Mailing Paper

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INFORMATION DISCLOSURE STATEMENT

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TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

In compliance with 37 C.F.R. §1.56, the patent documents listed on the attached Form PTO/SB/08A are being submitted herewith for consideration by the Examiner. In accordance with 37 C.F.R. 1.98, a copy of each of the listed items, other than U.S. Patents and U.S. Patent Application Publications, is included herewith.

The references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art.

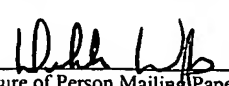
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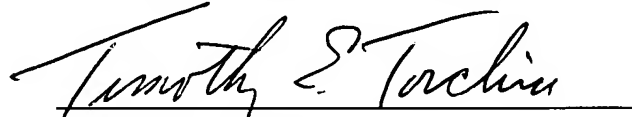
  
\_\_\_\_\_  
Signature of Person Mailing Paper  
Deborah Wilkes  
\_\_\_\_\_  
Name of Person Mailing Paper

on the merits. Accordingly, neither a statement nor a fee under 37 C.F.R. 1.97(c) is required. If Applicants are mistaken, and the mailing date of the first Office Action on the merits precedes the filing of this Supplemental Information Disclosure Statement, Applicants authorize that the fee due under 37 C.F.R. 1.17(p) be charged to Deposit Account No 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

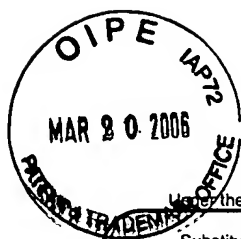
Respectfully Submitted

AMYLIN PHARMACEUTICALS, INC.

Dated: 09 Mar 06

  
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PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/559,595
Filing Date	November 30, 2005
First Named Inventor	ONG, John, et al
Art Unit	1654
Examiner Name	Not Yet Assigned
Attorney Docket Number	0501-UTL-0

Sheet 1 of 4

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1	US- 4,476,116	10-09-1984	SHABBIR, T. Anik	
	2	US- 4,847,240	07-11-1989	RYSER, et al	
	3	US- 5,116,817	05-26-1992	SHABBIR, T. Anik	
	4	US- 5,124,314	06-23-1992	COOPER, Garth J. S.	
	5	US- 5,367,052	11-22-1994	COOPER, Garth, et al	
	6	US- 5,512,549	04-30-1996	CHEN, Victor J.	
	7	US- 5,554,388	09-10-1996	ILLUM, Lisbeth	
	8	US- 5,574,008	11-12-1996	JOHNSON, William, et al	
	9	US- 5,788,959	08-04-1998	SINGH, Manish	
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	11	US- 5,686,411	11-11-1997	GAETA, Laura, et al	
	12	US- 5,705,483	01-06-1998	GALLOWAY, John, et al	
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	15	US- 5,977,070	11-02-1999	PIAZZA, Christin, et al	
	16	US- 5,981,488	11-09-1999	HOFFMANN, James	
	17	US- 6,294,153	09-25-2001	MODI, Pankaj	
	18	US- 6,391,318	05-21-2002	ILLUM, Lisbeth, et al	
	19	US- 6,440,392	08-27-2002	STERN, William	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	20	JP 1998095738 A	04-14-1998	MORIMOTO, Y., et al		✓
	21	JP 2000281589 A	10-10-2000	MORIMOTO, Y., et al		✓
	22	WO 99/07404 A1	02-18-1999	BEELEY, Nigel, et al		
	23	WO 99/25727 A2	05-27-1999	BEELEY, Nigel, et al		
	24	WO 99/25728 A1	05-27-1999	BEELEY, Nigel, et al		
	25	WO 00/41546 A2	07-20-2000	YOUNG, Andrew, et al		

Examiner  
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STATEMENT BY APPLICANT**

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Sheet 2 of 4**Complete if Known**

Application Number	10/559,595
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Art Unit	1654
Examiner Name	Not Yet Assigned
Attorney Docket Number	0501-UTL-0

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	26	US- 6,528,486	03-04-2003	LARSEN, Bjame, et al	
	27	US- 6,610,824	08-26-2003	GAETA, Laura, et al	
	28	US- 2002/0137666 A1	09-26-2002	ROBERT, Nigel, et al	
	29	US- 2002/0141985 A1	10-03-2002	PITTNER, Richard, et al	
	30	US- 2003/0087820 A1	05-08-2003	YOUNG, Andrew, et al	
	31	US- 2003/0087821 A1	05-08-2003	ROBERT, Nigel, et al	
	32	US- 2003/0220243 A1	11-27-2003	GLAESNER, Wolfgang, et al	
	33	US- 2004/0053819 A1	03-18-2004	DODD, Steven, et al	
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	34	WO 00/66629 A1	11-09-2000	YOUNG, A., et al		
	35	WO 01/04156 A1	01-18-2001	LARSEN, B., et al		
	36	WO 01/98331 A2	12-27-2001	GLAESNER, W., et al		
	37	WO 02/47712 A2	06-20-2002	PITTNER, R., et al		
	38	WO 02/48192 A2	06-20-2002	MILLICAN, R., et al		
	39	WO 03/026591 A2	04-03-2003	COWLEY, M., et al		

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Sheet	3	of	4	Attorney Docket Number	0501-UTL-0

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	40	CALLENS, C., et al, "Evaluation of Starch-Maltodextrin-Carbopol 974 Mixtures for the Nasal Delivery of Insulin in Rabbits", J. Control Release, 2000, pp 215-220, Vol. 66(2-3)	
	41	DAVIS, S. and ILLUM, L., "Absorption Enhancers for Nasal Drug Delivery", Clin Pharmacokinet., 2003, pp 1107-1128, Vol. 42(13)	
	42	DYER, A.M., et al, "Nasal Delivery of Insulin Using Novel Chitosan Based Formulations: A Comparative Study...", Pharm Res., 2002, pp 998-1008, Vol., 19(7)	
	43	FERNANDEZ-URRUSUNO, R., et al, "Enhancement of Nasal Absorption of Insulin Using Chitosan Nanoparticles", Pharm Res., 1999 Oct., pp1576-1581, Vol. 16(10)	
	44	ILLUM, L., et al, "Chitosan as a Novel Nasal Delivery System for Peptide Drugs", Pharm Res., 1994 Aug, pp 1186-1189, Vol. 11(8)	
	45	KYTE, J., et al, "A Simple Method for Displaying the Hydropathic Character of a Protein", J Mol Biol., 1982 May, pp 105-132, Vol. 157(1)	
	46	McEWAN, G.T., et al, "Polycation-Induced Enhancement of Epithelial Paracellular Permeability...", Biochem Biophys Acta., 1993 May 14, pp 51-60, Vol. 1148(1)	
	47	MIYAMOTO, M., et al, "Improved Nasal Absorption of Drugs Using Poly-L-Arginine: Effects of Concentration...", Eur J Pharm Biopharm, 2001 July, pp 21-30, Vol. 52(1)	
	48	MIYAMOTO, M., et al, "Effect of Poly-L-Arginine on the Nasal Absorption...", Int J Pharm., 2001 Sep 11, pp 127-138, Vol. 226(1-2)	
	49	NATSUME, H., et al, "Screening of Cationic Compound as an Absorption Enhancer...", Int J Pharm., 1999 Aug 5, pp 1-12, Vol. 185(1)	

Examiner Signature		Date Considered	
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	50	OHTAKE, K., et al, "Analysis of Transient and Reversible Effects of Poly-L-Arginine on the In Vivo Nasal...", J Control Release, 2002 Aug 21, pp 263-275, Vol. 82(2-3)	
	51	OHTAKE, K., et al, "Poly-L-Arginine Enhances Paracellular Permeability Via Serine/Threonine Phosphorylation..." Pharm Res., 2003 Nov., pp1838-1845, Vol. 20(11)	
	52	UCHIDA, D.A., et al, "Cationic Proteins Increase the Permeability of Cultured Rabbit Tracheal Epithelial..." Exp Lung Res., 1996 Jan - 1996 Feb, pp 85-99, Vol. 22(1)	

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